REMARKS/ARGUMENTS

Reconsideration of this application is requested. Claims 14-29 remain active in the application.

Claims 14, 15 and 16 are amended and directed to preferred aspects of the disclosure. In these claims the minimum amount of DOPE is increased to 60% (basis: page 5, line 12; see also claims 27-29) and the upper limit of polysorbate 80 decreased to 40% (basis: page 5, line 14, see also claims 27-29).

In the passage bridging pages 2 and 3 of the Office Action the Examiner indicates that he considers the declaration previously submitted to be insufficiently forthright to overcome his interpretation of the prior art. He further submits that micelles can adopt non-lamellar form such that the "emulsions or micelles" of Liu might form a non-lamellar phase structure. This seems a rather harsh view of the information provided.

The Inventor's opinion stated in his declaration is based upon many years of experimental work with systems of the invention and with systems similar to those of Liu. From this background it is the Inventors strongest belief that the systems described in Liu will not form non-lamellar particles as stated in the present claims. Nonetheless, given the potential penalties for misstatement nobody could be expected to state as fact in a declaration something that had not been tested experimentally in this exact system, since all scientific understanding is forever progressing by being challenged by unexpected results. It is clear, however, that the additional "evidence" found by the Examiner to contradict the Inventor's view is not of relevance in this case, as described below.

In section 1 of the Office Action, the Examiner considers that claims 14 and 17-28 are obvious over Liu in view of Unger and Landh. This is on the basis that formulation #17 of Liu contains (along with an overwhelming quantity of other components) equal amounts of DOPE and Polysorbate 80. Liu does not indicate that the composition forms non-lamellar particles (and

indeed the Inventor believes this not to be the case as indicated in his declaration) but the Examiner considers this to be inherent in view of Unger.

In the present claims as above amended, the amount of DOPE is limited to being 60% or greater and the amount of polysorbate 80 is limited to being 1 to 40%. Thus it is clear that no composition taught towards in Liu could possibly fall within the present claims either compositionally or structurally. The phase behavior of Liu is thus now moot because this document would still not provide compositions within the present claims.

With regard to the issue of structure, please note that the present invention requires the formation of "non-lamellar particles". These are well understood by those of skill in the art and are clearly described in the application, for example at page 6 where it is stated:

> " Where a particle is described as having a non-lamellar phase or structure, this indicates that at least the particle interior has this structure."

Applicants' claims, of course, are interpreted in light of the specification. Thus, the particles of the present invention have an *internal structure* which is non-lamellar. In contrast, a micelle is a very well defined and understood lipid particle in the form of a "drop" in which all of the lipid "head" groups are outermost and the "tail" groups form a non-polar core. Attached is a copy of an extract from p143 of "The Language of Shape" by Stephen Hyde et al. (1997 ISBN 0 444 81538 4) which would be a standard background text for a student in this area of technology.

It is clear that no non-lamellar structure can form *within* a micelle because there are only "tail" groups in this region. Thus a non-lamellar particle must have an interior populated by a structure of head and tail groups in a non-lamellar arrangement such as a liquid crystal.

The Examiner points to the disclosure of Unger and believes that this indicates micelles to potentially adopt a liquid crystalline structure. However, this structure is not a structure of *non-lamellar particles*. In fact the structure described in Unger is a non-lamellar *bulk phase*

formed *from an arrangement of particles*. Applicants respectfully emphasize to the Examiner that the coming together of particles to form a non-lamellar bulk phase does not alter the internal structure of the particles and that it is this latter property which is the concern of the present claims. The teaching of Landh is not concerned with particles of DOPE and P80 and thus does not appear to add anything of relevance to the above teachings.

Reconsideration and favorable action are solicited. Should the Examiner require further information, please contact the undersigned.

Respectfully submitted,

NIXON & VANDERHYE P.C.

By: _____
Arthur R. Crawford
Reg. No. 25,327

ARC:eaw
901 North Glebe Road, 11th Floor
Arlington, VA 22203-1808
Telephone: (703) 816-4000
Facsimile: (703) 816-4100

Attachment: Stephen Hyde, et al; "The Language of Shape"; *Elsevier Science B.V.* (1997)

THE LANGUAGE OF SHAPE

THE ROLE OF CURVATURE IN CONDENSED MATTER: PHYSICS, CHEMISTRY AND BIOLOGY

STEPHEN HYDE

DEPARTMENT OF APPLIED MATHEMATICS
INSTITUTE OF ADVANCED STUDIES
AUSTRALIAN NATIONAL UNIVERSITY
CANBERRA, 0200, AUSTRALIA

STEN ANDERSSON

SANDVIK RESEARCH INSTITUTE
S. LÅNGGATAN 27
38074 LÖTTORP, SWEDEN

KÅRE LARSSON

DEPARTMENT OF FOOD TECHNOLOGY
LUND UNIVERSITY
BOX 124, 22100 LUND, SWEDEN

ZOLTAN BLUM

DEPARTMENT OF INORGANIC CHEMISTRY
LUND UNIVERSITY
BOX 124, 22100 LUND, SWEDEN

TOMAS LANDH

DEPARTMENT OF FOOD TECHNOLOGY
LUND UNIVERSITY
BOX 124, 22100 LUND, SWEDEN

SVEN LIDIN

DEPARTMENT OF INORGANIC CHEMISTRY
LUND UNIVERSITY
BOX 124, 22100 LUND, SWEDEN

BARRY W. NINHAM

DEPARTMENT OF APPLIED MATHEMATICS
INSTITUTE OF ADVANCED STUDIES
AUSTRALIAN NATIONAL UNIVERSITY
CANBERRA, 0200, AUSTRALIA

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is recognised that condensed molecular aggregates consist of discrete building blocks even if the molecules are melted. The shape of those blocks sets the local interfacial geometry, while the composition of the molecular system constrains the global topology of the interface.

In the next few pages we shall discuss the question of local interfacial structures bounding idealised aggregates, tiled by blocks of fixed dimensions. The model represents one extreme idealisation of the molecular constituents that form the aggregate, most applicable to small surfactant molecules. At the other extreme, the block dimensions are not set *a priori*, they must be determined as a function of the temperature, concentration, etc. This case will be dealt with later. The welding of two concepts, a fluid-like mixture of hydrocarbons, with that of an idealised block is at first sight contradictory. However it can be shown to be consistent in a first order theory [2].

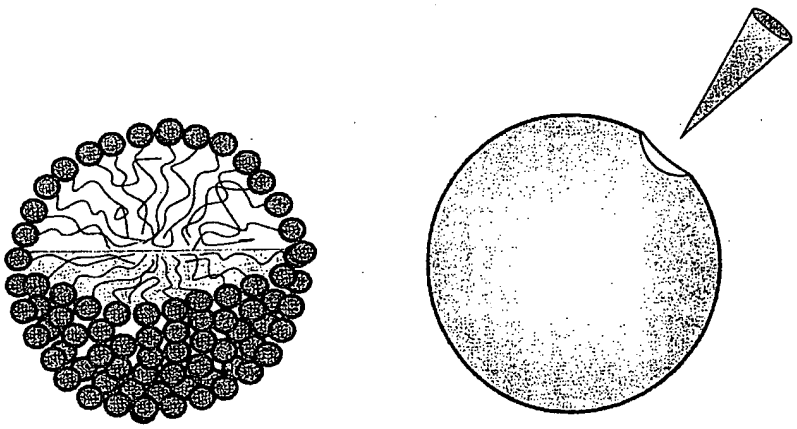

Figure 4.1: A schematic view of a spherical micelle. The hydrocarbon fraction of the surfactant molecules occupies the interior, and the sphere (by convention) divides the polar from hydrocarbon regions. If the micelle is built up from a number of equivalent building blocks, each such entity adopts the form of a cone.

4.2 *The local geometry of aggregates*

Since the suggestion of Hartley in the 30's that surfactants can self-assemble to form globular aggregates - micelles - in which the hydrophobic chains are essentially molten, it has been clear that in order for surfactant molecules to pack into aggregates, the molecular dimensions must be compatible. For